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Abstract
This paper examines the state of the single market in the European Union (EU) for pharmaceuticals. As with other products, the EU has adopted a number of institutions and policies to encourage integration and the free movement of goods. Over time, member states are more similar in the availability of pharmaceutical products, as well as in the patents that protect them. New pharmaceuticals are generally available sooner and in more EU members. However, there are large differences in the number and mix of products across member states. Because the pricing of pharmaceuticals remains a national competence, price variation also persists—though this may be desirable from a social welfare standpoint.

Keywords European Union · Integration · Intellectual property · Parallel trade · Pharmaceuticals · Regulation

1 Introduction

This paper examines the state of the single market in the European Union (EU) for pharmaceuticals. As with other products, the EU has adopted a number of institutions and policies to encourage integration and the free movement of goods. Pharmaceuticals differ from most other products, however, in several important respects. First, they are highly regulated. Second, their consumption is influenced by agency problems. Doctors and pharmacists act as gatekeepers, and insurance introduces moral hazard. Third, the extent of state involvement in their purchase is significant—including influence over prices. Finally, the reliance on patents and other forms of intellectual property is greater than in most other sectors.

This research draws on data of marketing authorizations, patenting, and sales to describe how the European pharmaceutical market has evolved since the establishment of the European Union. I show that over time, member states are more similar

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in the availability of products, as well as in the patents that protect them. New pharmaceuticals are generally available sooner. Regulatory harmonization and the centralized approval procedure appear to have played an important role. However, significant differences persist in the availability of older products and of generic versions of older drugs, which benefit less from EU institutions.

Similarly, the patent landscape has become more similar across member states. European institutions such as the European Patent Office (EPO) have reduced the cost of obtaining protection in multiple countries. Greater similarity of IP contributes to the development of a single market, although the effects are more evident for recent products that still benefit from patent protection.

However, pricing of pharmaceuticals remains a national competence: Member states are free to control drug prices within their borders. Price variation remains, despite the potential for arbitrage of differences through parallel trade. For example, the median German price is 43% higher than in Greece, while Bulgaria has median prices that are 67% of the German level. While the early 2000s saw some convergence in prices, the gap has not narrowed in recent years. This may be desirable from a social welfare standpoint, however, if it facilitates access to new products in poorer member states.

2 Peculiarities of Pharmaceutical Markets

Efficient markets generally require many buyers and sellers that trade with full information. Because drug quality is difficult for a consumer—whether patient, doctor, or pharmacist—to assess, countries generally regulate entry by requiring evidence of safety and efficacy before products are marketed. Because patients may lack the necessary expertise to choose appropriate treatments, many pharmaceutical products require a doctor's prescription. Both patients and doctors may be unaware of prices, or insensitive to them. To avoid distortions in prescribing that is tied to financial self-interest, doctors usually do not sell the drugs that they dispense; rather, pharmacists assume this responsibility. Patients in most developed countries and in all of Europe are at least partially covered by national health insurance, so they rarely face the full price of pharmaceutical treatments. The resulting moral hazard is one reason why governments often intervene in pricing.

Pharmaceutical development is characterized by large fixed costs—primarily clinical trials—most of which end in failure. Once a safe and effective molecule has been identified, however, marginal costs of production are low (relative to fixed costs) and imitation is easy, especially since the regulation of product quality precludes much reliance on trade secrets. Consequently, patents and other forms of intellectual property (IP) are more important in this sector than in most others.

Pharmaceutical markets often see competition between oligopolistic firms: each produces a differentiated patent-protected product to treat a particular disease and sells to monopsonistic buyers, in a highly regulated setting. Although pharmaceutical markets are global—in the sense that a safe and effective drug in one country should be equally safe and effective in others—the existence of country-level regulations and policies in addition to heterogeneous needs or patient demand implies

potential variation across countries. As described below, many of these country regulations and policies have evolved in Europe with the goal of creating a single market.

3 Convergence in Product Availability

Pharmaceutical products are highly regulated in Europe and all other developed countries. In particular, manufacturers must receive marketing authorizations in order to sell their products. These authorizations are granted on the basis of clinical evidence for safety and efficacy and acceptable manufacturing, and specify the conditions of sale: prescription or over-the-counter, for what indications, etc. National regulations or standards can differ from country to country, and national regulators occasionally reach different conclusions about a product's quality.

Critical to the creation of a single European market in pharmaceuticals is the harmonization of these regulatory requirements across member states. There now exist three regulatory pathways for drug approval in the European Economic Area (EEA).[1] The decentralized procedure allows an applicant to seek approval from each national regulator. Although each regulatory agency should now apply similar criteria for safety and efficacy, separate national reviews likely increase the cost for applicants. A second pathway, which exploits the harmonization of regulatory requirements, allows an applicant to apply to a single national regulator, designated the reference member state. Other national regulatory bodies where subsequent approval is sought then recognize the decision of the reference member state. This mutual recognition procedure (MRP) allows firms to apply first in countries where agencies have faster review times, or where speed-to-market is relatively important. The third—and now most important—pathway is the centralized procedure handled by the European Medicines Agency (EMA), which was created in 1995. Certain categories of products must use this pathway, including treatments for cancer and HIV as well as biologics.[2] With the centralized procedure, a firm receives a marketing authorization for all EEA member states; the product is identical across all member states; and product information is provided in all EU languages.

Receiving a marketing authorization is often only the first step in making a product available. The second step involves negotiating a product's price and conditions for reimbursement. Importantly, pricing and reimbursement are *national* competencies in the EU. That is, while member states respect the same criteria for approval (via the mutual recognition or centralized pathways), each country may reach different conclusions about a drug's value or importance, or have different priorities in treating diseases. This can result in divergence across countries in the decision to reimburse and at what price.

[1] The EEA includes all EU member states as well as Iceland, Liechtenstein and Norway. Switzerland, a party to the European Free Trade Association, is not an EEA member.

[2] Biologics are products derived from biotechnology processes.

Table 1 Products by country

Country	Available		Not available	
	N	Share	N	Share
Austria	2096	0.23	7193	0.77
Belgium	1890	0.20	7452	0.80
Bulgaria	1506	0.16	7767	0.84
Croatia	1337	0.14	8058	0.86
Czech Republic	1816	0.19	7628	0.81
Estonia	1059	0.11	8245	0.89
Finland	1469	0.16	7975	0.84
France	2365	0.26	6713	0.74
Germany	3496	0.39	5518	0.61
Greece	1614	0.17	7766	0.83
Hungary	1496	0.16	7880	0.84
Ireland	1449	0.16	7777	0.84
Italy	2613	0.28	6822	0.72
Latvia	1515	0.16	7757	0.84
Lithuania	1424	0.15	7890	0.85
Luxembourg	1398	0.16	7520	0.84
Norway	1923	0.20	7524	0.80
Poland	2039	0.22	7122	0.78
Portugal	2178	0.23	7235	0.77
Romania	1460	0.16	7802	0.84
Slovakia	1644	0.18	7722	0.82
Slovenia	1622	0.17	7813	0.83
Spain	2551	0.27	6805	0.73
Sweden	1489	0.16	7959	0.84
UK	2007	0.22	7058	0.78

Calculations based on IMS MIDAS data for 2016, using the countries for which I have data (notably, this excludes the Netherlands and Denmark). A product is defined as dosage form and strength of a unique chemical, biologic, or combination. Products classified as Kanpo or Chinese therapies, homeopathic therapies, antiseptics for non-human use, or dietetic agents are excluded

Member states take a variety of approaches to pricing and reimbursement.[3] Some, like France, opt for explicit price controls. Others use indirect mechanisms. For example, the National Institute for Clinical Evidence (NICE) in the UK evaluates a product's cost-effectiveness to determine whether to recommend that the British National Health System reimburse the product. Since manufacturers have some idea of the threshold that is used, they understand that there is an implicit cap on what price they can charge. The criteria for determining price can differ from country

[3] For a more detailed discussion of these policies, see OECD (2008), for example.

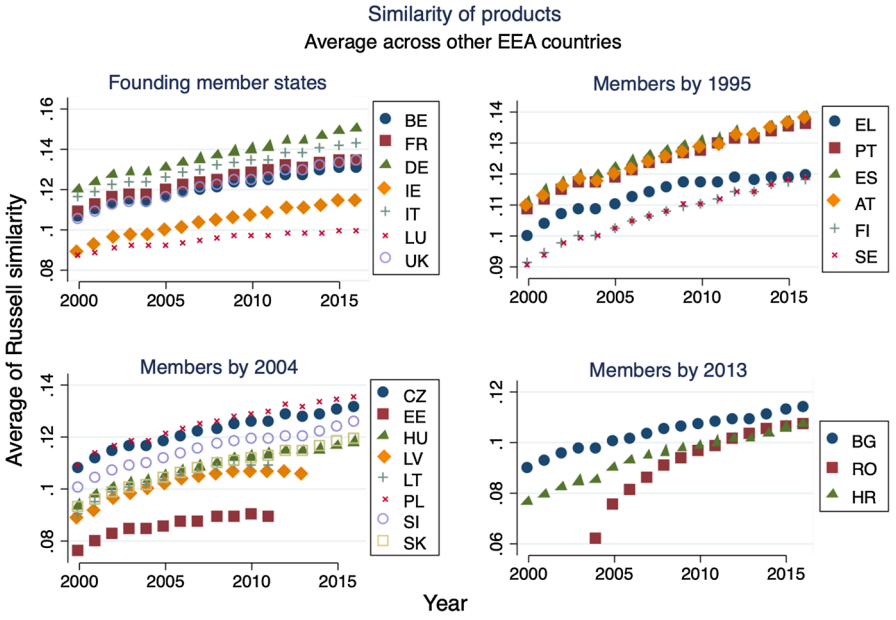

Fig. 1 Trends in product similarity

to country. Most now employ some type of health technology assessment, but may require different evidence or trials for those assessments.

Heterogeneity in product mix is evident in Table 1, which considers all products sold in at least one of the listed countries in 2016. For each country, "available" products are those that had positive sales, and "unavailable" are those that had positive sales elsewhere in Europe but not in the focal country. While some of the variation is an artifact of data availability and classifications,[4] no country has more than two-fifths of the total products available in Europe.

Despite these differences, have pharmaceutical product markets increased in similarity over time? To assess this, I calculate the Russell–Rao binary similarity coefficient for all possible country pairs, from 2000 to 2016. This coefficient is the proportion of pharmaceutical products that are available in both countries out of all products available somewhere in my sample of countries. Figure 1 graphs the average of this coefficient between a focal country and all others. Clearly, the average similarity between a country and other member states has grown over time.

Table 2 summarizes the outcomes for new chemical entities (NCEs) that were introduced somewhere in the world from 1990 through mid-2016. The second column provides the number of NCEs first launched in each year. The third column shows how many of those NCEs used the EMA's centralized procedure, and the fourth column indicates how many were launched somewhere in the EEA. "Average years to first EEA" shows the average lag between the first global launch and the

[4] In a few countries, only the retail or hospital segment is included.

Table 2 Regulatory pathways and time to approval

Global launch	N NCE	N centralized	N EEA approval	Avg years to first EEA	Avg years to EEA countries	Avg number EEA countries
1990	36	0	31	2.44	5.82	9.78
1991	43	1	30	0.45	2.71	10.26
1992	44	0	31	1.69	5.75	8.07
1993	37	5	32	1.56	4.66	11.89
1994	38	2	24	2.69	5.55	7.61
1995	40	7	30	1.37	4.40	12.45
1996	43	13	36	0.56	2.72	14.93
1997	48	12	41	0.76	2.08	12.21
1998	45	26	38	1.55	2.91	13.51
1999	41	15	27	1.36	2.50	11.68
2000	41	17	33	1.08	2.78	11.51
2001	33	19	27	0.04	0.84	15.00
2002	34	17	28	0.72	2.52	15.56
2003	25	15	21	0.70	1.56	14.92
2004	23	10	18	0.35	1.35	13.96
2005	29	17	22	1.05	2.39	12.41
2006	31	22	25	1.26	1.87	13.19
2007	29	21	24	0.65	1.28	13.14
2008	24	15	17	1.29	1.76	11.58
2009	36	25	27	0.59	1.26	12.19
2010	24	18	16	0.33	1.23	10.62
2011	33	24	25	0.82	1.11	11.73
2012	28	18	18	0.63	0.90	7.75
2013	38	28	24	0.54	0.96	7.45
2014	43	33	32	0.33	0.71	7.07
2015	37	23	21	0.20	0.41	4.41
2016	18	8	6	0.07	0.15	0.83
Total	941	411	704	0.99	2.51	11.02

Calculations are based on data from IMS Lifecycle and EMA. EEA refers to the set of EEA countries as of 2016. Global launch is the first year in which the product was launched anywhere in the world. Some NCEs were evaluated using the centralized procedure, but not approved. The final three columns are conditional on any EEA launch

first EEA launch, while the next column presents the average lag between the first global launch and all EEA countries in which the drug was eventually introduced. Prior to 1995, the centralized procedure did not exist, and most products that were first launched globally during the 1990s used the decentralized or mutual recognition pathways. Over time, an increasing share of products has been approved by the EMA, which has resulted in faster access to new products in Europe. For example, the first approval in the EEA occurred within about 6 months of a product's initial

Table 3 Non-centralized marketing authorizations by country

Country	New drug		Biologic		Generic	
	RMS	CMS	RMS	CMS	RMS	CMS
Austria	0.02	0.49	0.08	0.52	0.03	0.12
Belgium	0.00	0.46	0.01	0.49	0.00	0.11
Bulgaria	0.00	0.13	0.00	0.25	0.00	0.07
Croatia	0.00	0.07	0.00	0.11	0.00	0.02
Czech Republic	0.00	0.23	0.00	0.22	0.02	0.05
Denmark	0.01	0.37	0.14	0.39	0.13	0.11
Estonia	0.00	0.22	0.00	0.22	0.01	0.06
Finland	0.00	0.44	0.00	0.44	0.05	0.09
France	0.04	0.44	0.06	0.40	0.01	0.12
Germany	0.24	0.46	0.31	0.31	0.18	0.25
Greece	0.00	0.51	0.00	0.47	0.01	0.09
Hungary	0.00	0.25	0.00	0.32	0.02	0.09
Iceland	0.00	0.31	0.00	0.15	0.01	0.05
Ireland	0.02	0.47	0.03	0.46	0.01	0.11
Italy	0.02	0.65	0.04	0.56	0.02	0.21
Latvia	0.00	0.24	0.00	0.24	0.00	0.06
Lithuania	0.00	0.21	0.00	0.19	0.00	0.07
Malta	0.00	0.19	0.00	0.19	0.01	0.04
Netherlands	0.13	0.38	0.05	0.40	0.16	0.11
Norway	0.00	0.40	0.00	0.40	0.01	0.07
Poland	0.01	0.29	0.00	0.38	0.02	0.16
Portugal	0.00	0.56	0.02	0.54	0.08	0.12
Romania	0.00	0.14	0.00	0.31	0.00	0.10
Slovak Republic	0.00	0.25	0.00	0.32	0.00	0.10
Slovenia	0.00	0.26	0.00	0.28	0.00	0.06
Spain	0.04	0.55	0.02	0.52	0.02	0.19
Sweden	0.19	0.33	0.06	0.47	0.07	0.11
United Kingdom	0.25	0.30	0.13	0.46	0.13	0.15

Figures are shares of the total number of non-centralized marketing authorizations issued. RMS indicates the country was the reference member state; CMS indicates the country was a concerned member state, referring to an initial authorization granted in the RMS

global launch between 2010 and 2014, compared to more than 20 months in the early 1990s. Similarly, the average time to approval across the EEA (conditional on launch) has fallen, and the average number of EEA countries in which a product is launched has increased.[5] For the entire sample, drugs approved by the EMA are launched in more than 15 countries, compared to fewer than 8 for the remainder.

[5] The decline observed in the most recent years is a result of truncated data: we have fewer years over which to observe launch decisions.

Table 4 Cox hazard model for time to launch (from first global launch), NCEs

	1 b/se	2 b/se	3 b/se
Post-EU membership	0.14***	0.03**	1.92***
	(0.01)	(0.01)	(0.03)
EMA procedure		0.92***	0.95***
		(0.02)	(0.02)
EMA procedure * EU member		0.44***	0.29***
		(0.02)	(0.02)
N	58,529	58,529	58,529
Log L	− 49,4402	− 487,821	− 484,783
Chi sq	218	13,380	19,456
Fixed effects			Country

*$p < 0.10$; **$p < 0.05$; ***$p < 0.01$. Based on launch dates provided in IMS Lifecycle Focus data

While Table 2 above demonstrate significant take-up of the EMA's centralized procedure, much of the stock of marketing authorizations cover products that were introduced before its creation in 1995, and that used the mutual recognition or decentralized procedures. Table 3 provides an overview of these marketing authorizations. The reference member state (RMS) is where an application is filed; concerned member states (CMS) are those in which mutual recognition was requested by the applicant, so that a marketing authorization exists. The unit of observation is a presentation (chemical or biologic composition, dosage form, and strength); there were more than 28,000 presentations as of March 2018.[6] Germany and the UK each account for about a quarter of the applications for new drugs, followed by Sweden and the Netherlands. These large shares could reflect the efficiency of the national regulators, or the relative ease of pricing compared to other countries (which has strategic importance for launch sequence, as will be discussed later). For generic applications, four countries have an outsize share: again the UK and Germany, as well as Denmark, Sweden and the Netherlands. An important difference between the MRP for new drugs and generics is that the former generates more authorizations in concerned member states. While recent member states have a smaller share (not surprisingly), many countries grant marketing authorizations for more than 40% of the new drugs that have been introduced elsewhere via the MRP. For generics, the share is much lower. On average, generic drugs approved via the MRP have marketing authorizations in only three member states; for new drugs, the average is nine.[7] Not only does this result in lower measured similarity between countries, but it also has important implications for parallel trade and generic competition, and thus prices.

[6] These data are derived from the Human MRIndex.

[7] This is higher than the average number of countries in which the drugs were launched because a marketing authorization provides the right—but not the obligation—to sell a product.

Table 5 Launch lags by country, NCEs

Country	Avg years to launch		
	Pre-EU	Post-EU	Total
Austria	4.21	1.70	2.09
Belgium		2.98	2.98
Bulgaria	6.41	2.08	5.58
Czech Republic	4.60	1.88	3.65
Denmark		1.83	1.83
Finland	3.96	1.66	2.03
France		2.43	2.43
Germany		1.64	1.64
Greece		3.20	3.20
Hungary	4.50	1.72	3.62
Ireland		2.54	2.54
Italy		2.61	2.61
Latvia	6.29	2.68	5.24
Luxembourg		4.17	4.17
Netherlands		1.65	1.65
Norway	2.56		2.56
Poland	5.07	1.70	4.07
Portugal		3.79	3.79
Slovak Republic	5.31	1.78	4.02
Slovenia	5.39	2.02	4.28
Spain		2.74	2.74
Sweden	2.67	1.46	1.68
UK		1.65	1.65
Total	4.70	2.25	2.91

Calculations are based on data from IMS Lifecycle. Figures are years since the initial global launch of an NCE

To evaluate the role of EU institutions in convergence of product markets, I focus on a sample of relatively recent NCEs. Table 4 presents results from a Cox proportional hazard model of the time to launch in country *i* from the first global launch of the product.[8] The sample includes all countries that were EU or EEA members in 2016 for which I have data. Time-varying covariates include whether country *i* was a member state at the time of the NCE's global introduction, as well as its interaction with an indicator variable for whether the NCE was approved via the centralized procedure (the EMA). Positive coefficients indicate faster "failure": i.e., a launch in country *i*. The results show that EU membership and the use of the EMA procedure are associated with an increase in the speed at which NCEs are available

[8] The specification is extremely parsimonious. Many other factors, including pricing and reimbursement policies, affect the decision to market a product and the speed of launch; I discuss these later in this paper.

in a country. One interpretation is that EU membership and institutions have reduced the fixed costs of market entry. The counterfactual here is not obvious; perhaps over time, clinical trial design has yielded less ambiguous results, or improved information technology has facilitated the analysis of these results. As a consequence, the increased launch speed could be simply a result of "easier" dossiers rather than a streamlined bureaucracy. However, during this time period, many biotechnology products (for which the centralized procedure is required) were introduced. These represented scientific novelty that was probably more challenging to evaluate.

Table 5 provides a clearer picture by country. The average number of years between the global introduction of an NCE and its availability locally fell for every country that joined the EU after 1992. In most cases, the reduction in launch lag was more than 2 years. Overall, especially for more recent EU members, the evidence points to benefits in access to pharmaceuticals that is linked to tighter integration.

4 The Intellectual Property Landscape

The importance of patents and other forms of intellectual property protection in providing innovation incentives in the pharmaceutical industry is well-established; recent studies of the influence of IP on innovative efforts in pharmaceuticals include Kyle and McGahan (2012) and Budish et al. (2015). Not only are patents and IP key determinants of the launch of new drugs (Cockburn et al. 2016), but their presence serves as a barrier to entry for generic competitors (Hemphill and Sampat 2012; DG Competition of the European 2009). IP thus affects the product mix both through the incentives to develop and launch new drugs as well as in the extent of generic copies. Consequently, a single market in pharmaceuticals is facilitated by uniformity in the treatment of IP protection for drugs. Indeed, changes to national patent law were a condition of membership for many countries that joined the EU.[9]

In general, drugs can be protected by a "product" patent that covers the chemical itself, as well as additional patents that cover manufacturing processes, methods of use, and other aspects. As a result of the 1995 TRIPS Agreement, all members of the World Trade Organization (including all EU countries) must provide a minimum of 20 years of patent protection from the date of application, and must protect pharmaceutical product patents. The product patent is available only if the chemical is truly novel, and is difficult to invent around. Product patent applications are usually filed early in the drug development process, which takes around 10–12 years for a new drug. The so-called secondary patents are weaker in the sense that competitors may be able to invent around them, and not all countries use the same criteria in considering them.

Because the lengthy development times substantially reduce the period of patent protection post-marketing authorization, many countries use complementary policies to reward innovation. One approach extends the term of protection for the product patent. In Europe, this is the supplementary protection certificate (SPC); in

[9] In recognition of the weaker protection for drugs that were marketed prior to a country's accession to the EU, derogation periods for parallel trade in pharmaceuticals applied to Bulgaria, the Czech Republic, Estonia, Hungary, Latvia, Lithuania, Poland, Portugal, Slovakia, Slovenia, and Spain.

the US, this is the Hatch-Waxman extension. Both provide a maximum of 5 years of additional protection past the original expiration date. In addition, regulators can grant "data exclusivity" to owners of marketing authorizations. During the period of exclusivity, competitors cannot rely on clinical data that are submitted by the original applicant when seeking approval of a generic copy—even if a patent has expired.

Just as there are multiple pathways for drug approval, there persists a dual system of patents: patent applicants can seek protection from a national patent office, or via the European Patent Office. A patent that is issued by the EPO is identical in all of the member states designated by the applicant, but enforcement (prior to the creation of the Unified Patent Court, which is expected soon) remains at the national level. Thus, patent status can vary across member states, for two reasons: first, an applicant may not seek protection in all countries. As Harhoff et al. (2009) show, translation, validation and renewal fees deter many EPO applicants from seeking protection outside of the largest member states. Second, without a Unified Patent Court, a patent can be invalidated in a subset of countries but remains in force in others. Cremers et al. (2016) present empirical evidence of inconsistencies across EU jurisdictions in patent litigation. While a harmonized policy on SPCs has existed since 1992, SPCs are granted at the national level. Countries are not required to recognize the SPC grant decisions that are taken elsewhere in the EU, and consequently SPC protection can also vary.

Finally, prior to 2005, data exclusivity terms differed across member states. Belgium, Germany, France, Italy, Luxembourg, the Netherlands, Sweden, and the UK provided 10 years of protection, while other EU members provided only six. The harmonized policy is now 8 years of data exclusivity plus 2 years of market exclusivity (during which competitors can file applications relying on originator data, but will not receive marketing authorizations), with an additional year of protection granted if an important new use is developed.

Table 6 provides an overview of patenting by country, based on patents that are identified as relevant to drugs either launched or in late stages of development. The first two columns represent the number of patent applications filed either at the EPO or at the local patent office. The third column indicates how many of these applications were ultimately granted a patent. While all EEA countries are EPO members, some joined later than others. The share of pharmaceutical patents that are handled by local patent offices is fairly small for most, with the exception of Norway (which joined the EPO only in 2008). The number of patents granted on pharmaceuticals varies considerably across countries. France, Germany and the UK have the largest number, which is not surprising given their size and patterns observed for European patents generally (Ménière et al. 2017). However, some relatively small countries—such as Belgium, Luxembourg, and the Netherlands—also have relatively high counts. Notably, "unique" patents, or those no equivalents identified in other EU countries, are rare. Similarity in patent protection has been increasing over time. Figure 2 shows the average of the simple matching binary similarity coefficient (i.e., the proportion of matches) of patents in force[10] between all pairs of countries over time; the figure shows a steady increase for most countries, particularly since the early 2000s.

[10] I define "in force" in year *y* as a granted patent that is not yet lapsed, expired, or invalidated.

Table 6 Patents by country, NCEs

Country	Total count of				
	EPO	Local	Grants	SPC	Unique
Austria	4063	198	3635	497	5
Belgium	4159	261	3792	408	6
Bulgaria (2002)	989	576	1138	75	67
Croatia (2008)	473	578	635	16	13
Cyprus (1998)	1774	444	1742	9	63
Czech Republic (2002)	975	1209	1484	137	0
Denmark (1990)	3115	920	3161	427	1
Estonia (2002)	995	273	849	114	1
Finland (1996)	2174	1078	2447	287	1
France	4246	309	3915	573	4
Germany	4013	563	3818	383	11
Greece (1986)	3376	368	3134	332	1
Hungary (2003)	913	1739	1683	113	4
Iceland (2004)	586	298	515	58	0
Ireland (1992)	2774	904	2970	381	4
Italy	4224	302	3892	688	10
Latvia (2005)	1453	243	1201	150	2
Lithuania (2004)	1531	104	1135	105	0
Luxembourg	3892	133	3403	497	1
Malta (2007)	260	50	175	15	0
Netherlands	4249	176	3723	489	2
Norway (2008)	181	2188	1475	253	4
Poland (2004)	714	1208	1264	68	3
Portugal (1992)	2784	737	2940	296	6
Romania (2003)	1539	415	1460	120	0
Slovak Republic	1000	972	1377	136	0
Slovenia (2002)	1736	170	1387	185	1
Spain (1986)	3551	631	3572	390	14
Sweden	4219	168	3737	522	1
UK	4222	335	3910	441	4
Total	70,180	17,550	69,569	8165	229

Calculations are based on data from IMS Lifecycle. Patent information is available for drugs that were in development since the early 1990s and that reached at least Phase II clinical trials

Protection by SPCs is far from uniform. There is heterogeneity in the granting of SPCs across countries; see Kyle (2017) for more details. To take a single example, consider the anti-epileptic drug vigabatrin. This drug received SPCs in nine countries, most of which extended national patents granted in 1976. In Italy, two different patentholders were granted SPCs on two different EPO patents from 1983 and 1984. Consequently, the SPCs expired at different dates, ranging from 1999 to 2009.

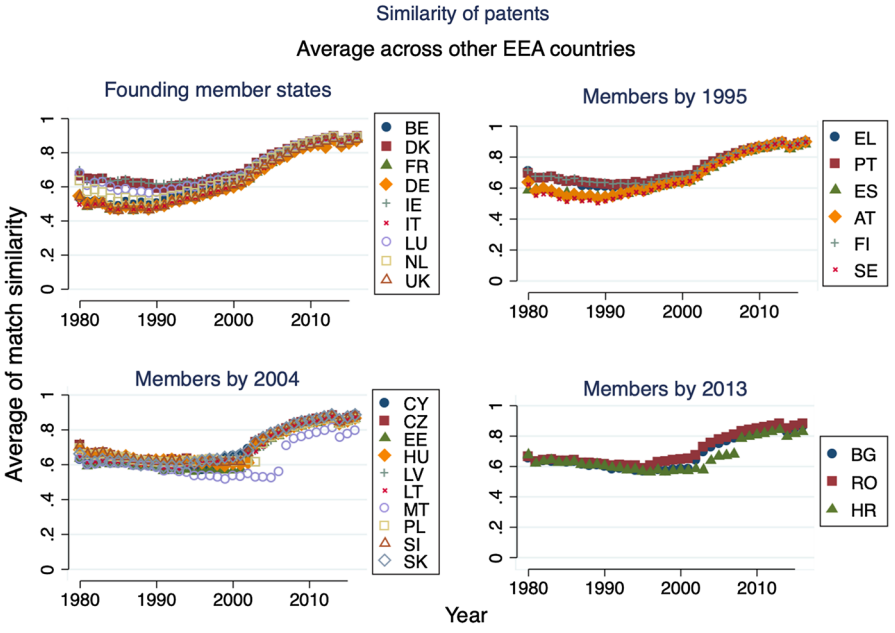

Fig. 2 Trends in patent similarity

Table 7 Regressions of patent grant

	1 b/se	2 b/se	3 b/se
Post-EPO membership	0.57***	0.57***	0.57***
	(0.00)	(0.00)	(0.00)
Post-EU membership	0.10***	0.12***	0.11***
	(0.00)	(0.00)	(0.00)
Product patent	0.03***	0.07***	0.07***
	(0.00)	(0.00)	(0.00)
Years since 1980		0.01***	
		(0.00)	
N	133,175	130,505	130,505
Adjusted R-sq	.428	.484	.486
Fixed effects			Year

*$p < 0.10$; **$p < 0.05$; ***$p < 0.01$

While this is not a typical case, it demonstrates the potential variation in IP barriers for the same product across EU countries. Column 7 of Table 6 shows that the number of products with SPCs ranged from nine in Cyprus to 688 in Italy. The incentive to seek an SPC is related to the importance of the pharmaceutical market in a country and the expected risk of generic competition, including the existence and strength of secondary patents locally.

Patent applications are an endogenous response to expectations of the patent's being granted; the size of the market relative to the cost of seeking protection; and the threat of generic competition. Some variation in IP protection is driven by the differences in these factors across countries. Additional variation is introduced for patents that are sought at national patent offices, which may reach different conclusions about the merits of a patent application, and by enforcement at the national level, as local courts may also reach different conclusions about patent validity and infringement. The EPO (and eventually the Unified Patent Court) is expected to reduce the effects of the latter; the incentive to patent may also be higher once a country is an EU member. These tendencies are shown in Table 7, which contains the result of a linear probability model for patent j being granted in country i. The EPO mechanism greatly increases the probability that a firm will seek and receive protection. EU membership has a smaller marginal effect, but still positive and significant. Product patents are more likely to be granted than others, which is also consistent with expectations.

5 Convergence in Prices

Price convergence is an important indicator of the integration of markets. Price differences across borders should be arbitraged away in the presence of free movement of goods, particularly when transportation costs are relatively small. The evidence on price convergence in the EU is mixed. Goldberg and Verboven (2005) conclude that the automobile market in Europe largely adheres to the law of one price, and Méjean and Schwellnus (2009) show that price convergence is significantly faster within the EU than in a control group of other countries. According to Eurostat, however, large price differences persist across EU member states, and price convergence among EU-28 countries slowed after 2008.[11]

Historically, many barriers to trade have existed for pharmaceuticals, of which two are especially important. The first is the regulation that was discussed above: A marketing authorization is required in order to sell pharmaceutical products, and prior to the EMA, these authorizations were granted at the national level. The second is the treatment of intellectual property and the rights of IP owners to control trade in their products, or the "exhaustion" policy. With national exhaustion, a producer cannot resort to IP rights to prevent resale of products once they are first offered in a national market, but the producer can use those rights to prevent importation of the same products from other countries. The EU introduced a policy of regional exhaustion: rights are exhausted once a product is sold in any member state. The removal of the IP barrier has created opportunities for parallel trade, the movement of IP-protected goods such as pharmaceuticals across borders in response to price differences. The legality of such trade and of various responses to it—e.g., rationing or dual-pricing contracts—have been the subject of numerous court cases within Europe. Generally, courts have maintained the importance of free movement of goods, and we would

[11] See Eurostat for more information and underlying data.

Table 8 EMA licenses for parallel distribution

Year	N			Avg number	
	Licenses	Drugs	Distributors	Destinations	Origins
1998	3	1	1	3.00	27.00
1999	34	12	9	1.50	21.35
2000	60	20	13	3.15	21.58
2001	116	27	15	3.03	22.83
2002	128	28	17	3.37	19.67
2003	125	42	17	2.82	21.03
2004	275	61	20	3.44	23.80
2005	697	90	36	3.44	24.60
2006	1405	127	44	4.73	26.38
2007	1507	149	47	4.79	26.75
2008	1349	172	60	4.06	26.54
2009	1651	213	67	3.81	26.77
2010	2083	246	67	4.11	27.05
2011	2028	256	71	4.17	27.42
2012	1799	257	80	4.20	27.44
2013	2169	317	83	3.91	27.40
2014	2406	345	87	3.83	28.13
2015	2643	361	95	3.99	27.98
2016	2831	404	86	4.00	28.33
2017	2531	420	105	3.89	28.20
Total	25,840	3548	1020	4.04	27.28

Based on licenses through 2017 as reported on the EMA parallel distribution register. A license corresponds to a single presentation (dosage form and strength) for the holder of a marketing authorization of a drug, and the countries of origin and destination are specified by the parallel distributor

expect price arbitrage and convergence towards a single European price under these conditions, even if some frictions from regulatory requirements persist. Unlike other IP-intensive products, however, pharmaceuticals are subject to substantial price regulation. This regulation can both contribute to—but also reduce—the extent of price variation across member states, as discussed below.

To market a parallel import, an importer must apply for a license either from the EMA (for centrally approved products) or from the national regulator in the country of destination (for products approved by the mutual recognition or the decentralized procedures). For the latter, obtaining information on licenses granted can be tedious; see Kyle (2016) for descriptive statistics for a few countries. Since 2015, the EMA has provided data on licenses for parallel distribution, which are summarized in Table 8 below. The centralized procedure facilitates parallel trade for two reasons. First, it reduces the transaction costs for a parallel trader that might sell in multiple destination countries. Second, the centralized procedure implies identical products in all member states. Otherwise, the parallel

Table 9 EMA parallel distribution licenses by country

Country	Sum	
	Destination	Origin
Austria	1010	24,736
Belgium	106	24,885
Bulgaria	3	12,140
Croatia	5	6584
Cyprus	3	16,914
Czech Republic	17	13,894
Denmark	2094	20,121
Estonia	0	11,498
Finland	448	22,286
France	147	24,910
Germany	11,844	14,247
Greece	0	25,008
Hungary	0	12,320
Iceland	0	17,234
Ireland	3749	23,019
Italy	77	25,024
Latvia	34	12,340
Lithuania	26	12,290
Malta	1267	18,161
Netherlands	2080	22,804
Norway	0	23,428
Poland	166	12,804
Portugal	8	24,813
Romania	15	13,152
Slovakia	0	13,097
Slovenia	0	11,464
Spain	176	24,879
Sweden	2925	20,205
United Kingdom	5486	22,526
Total	31,686	526,783

Based on licenses through 2017 as reported on the EMA parallel distribution register. A license corresponds to a single presentation (dosage form and strength) for the holder of a marketing authorization of a drug, and the countries of origin and destination are specified by the parallel distributor

trader must identify products that have the same chemical composition, dosage form, and strength in both the origin and destination markets, and may have to relabel or repackage the product in order to adapt it to the local market. As shown in Kyle et al. (2008), one response by originators to the threat of parallel imports is to differentiate their products across markets, as this raises costs for parallel traders. With the increased use of the centralized procedure, the costs of engaging

Table 10 Summary statistics for price variation, pack level

Variable	Mean	SD	Min.	Max.	N
All products					
Coefficient of variation	0.37	0.26	0	3.10	728,195
Interquartile range	2.30	34.82	0	8840.00	2,106,531
Originator products					
Coefficient of variation	0.33	0.24	0	2.69	481,579
Interquartile range	3.14	43.35	0	8840.00	1,183,557
Generic products					
Coefficient of variation	0.42	0.28	0	2.72	344,376
Interquartile range	0.99	16.19	0	2382.57	1,275,855

Table 11 Summary statistics for price variation, drug level

Variable	Mean	SD	Min.	Max.	N
All products					
Coefficient of variation	0.53	0.4	0	4.41	184,505
Interquartile range	6.49	66.98	0	7035.5	340,919
Originator products					
Coefficient of variation	0.45	0.33	0	3.74	116,252
Interquartile range	9.9	89.53	0	7035.5	179,154
Generic products					
Coefficient of variation	0.59	0.41	0	3.87	113,423
Interquartile range	2.63	22.93	0	1205.61	240,301

in parallel trade have likely fallen, which is consistent with the rise in the number of licenses, the number of drugs concerned, and the number of parallel trading firms (parallel distributors) over time. In addition, the expansion of the EU to countries with historically low prices may have increased the arbitrage opportunities, as these countries became potential origins of parallel trade.

However, the number of destination markets has not changed much, and the set of countries to which parallel imports flow is rather small: as shown in Table 9 shows, Germany is listed as a destination in 11,844 of the 25,844 licenses granted, followed by the UK, Sweden, Denmark, the Netherlands, and Ireland. The information on origins is less illuminating, as most applicants list all countries that are not designated as destinations.[12]

Tables 10 and 11 below provide an overview of price dispersion in the EU.[13] In Table 10, I calculate the price per "standard unit" (such as a pill or capsule), in euros, of a molecule-dosage form-strength presentation, which is as close to an

[12] Occasionally, countries are listed as both origins and destinations, most often Ireland, Malta, and the UK.

[13] Note: Calculations based on data from IMS MIDAS, 2002-2016, using data for Austria, Belgium, Bulgaria, the Czech Republic, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Luxembourg, Norway, Poland, Portugal, Slovakia, Slovenia, Spain, Sweden, and the UK. Calculations use the entire set of countries, including periods prior to their EU membership.

"apples-to-apples" comparison as is possible across markets; while the manufacturer or brand name may vary across countries, the product itself is homogeneous. These calculations exclude outliers, which are defined as those observations for which the calculated price was more than 100 times greater or less than the EU average, which typically occur where sales are very low and are likely to be caused by measurement errors. However, small countries, which are more likely to have low sales, are disproportionately affected by this. The coefficient of variation is 0.37. For comparison, the coefficient of variation for other products in 2016 among the 28 EU member states ranged from 0.064 for consumer electronics to 0.254 for electricity and other fuels (Eurostat 2017). There is relatively more variation in the prices of generic products than for originator products, although the price level of the latter is much higher on average.

Results for relative prices or price variation depend on whether the unit of comparison is a pack or a quantity-weighted average across all packs or presentations (chemical-dosage form-strength combinations). There are two reasons: First, drugs are often sold in different presentations across countries. To take a simple example, a pair of countries may have no identical presentations, even if the drug is sold in both countries. In this case, there is no relative price per pack, but there is a relative price per drug. Second, the drug-level comparison uses quantity-weighting across presentation, while the package-level comparison gives each presentation equal weight. To the extent that manufacturers strategically adapt products to local markets—which thus reduces the number of countries in which an equivalent molecule-dosage form-strength is sold—the pack-level approach likely understates the variation across countries.[14] Table 11 presents the same information, this time calculated as the quantity-weighted average price per standard unit across all presentations of a drug. All measures of price variation are higher than those at the package level, with the same general pattern: generic products again show more price dispersion than do the originator products.

Tables 12, 13, 14 and 15 show how relative prices vary across countries. In each column, I show the average ratio of the country's price to the EU mean for originator and generic products, as well as the quantity-weighted average with parallel imports included. The first three columns include all observations, while the next three exclude outliers as defined above. Since each product has equal weight in the calculation of averages across countries, products with a small number of units sold but an extreme price can have a large influence. While measurement error is especially problematic where sales are low (due to rounding), these outliers may sometimes be accurate. They may reflect product shortages, for example, and the UK and other EU countries have recently launched investigations into excessive pricing of a number of generic products.

Note that the set of products varies by column and row, as not all products are available in all countries. Firms might sell one package in high price markets, and a different package in low price countries. I thus separate the sample into packages that were launched in relatively few markets (fewer than ten countries, Table 12)

[14] About 30% of the observations in my dataset are sold in a single country, for example, though close equivalents may be available elsewhere.

Table 12 Prices relative to EU mean, at pack level, products in fewer than 10 countries

Country	All observations			Outliers excluded		
	Originator	Generic	Total	Originator	Generic	Total
Austria	1.02	1.15	1.03	1.00	1.06	1.03
Belgium	0.99	1.33	1.02	0.99	1.10	1.02
Bulgaria	0.91	1.14	0.94	0.98	0.95	0.95
Czech Republic	0.82	0.93	0.87	0.88	0.91	0.87
Finland	1.05	1.30	1.07	1.01	1.12	1.06
France	1.07	1.32	1.06	1.05	1.12	1.06
Germany	1.02	1.12	1.02	0.99	1.05	1.02
Greece	0.87	1.02	0.91	0.88	0.99	0.91
Hungary	0.91	0.96	0.89	0.90	0.93	0.90
Ireland	1.05	1.24	1.06	1.04	1.09	1.07
Italy	1.01	1.13	0.99	0.97	1.04	1.00
Luxembourg	1.21	1.29	1.06	1.00	1.07	1.06
Norway	1.01	1.27	1.03	0.95	1.06	1.00
Poland	0.87	0.97	0.91	0.93	0.93	0.91
Portugal	0.94	1.09	0.96	0.93	1.03	0.97
Slovak Republic	0.91	1.01	0.95	0.97	0.96	0.95
Slovenia	1.05	1.16	1.05	0.98	1.10	1.04
Spain	0.90	1.02	0.92	0.91	0.97	0.92
Sweden	1.02	1.23	1.03	1.00	1.04	1.03
UK	1.13	1.16	1.05	1.04	1.06	1.05

Data are quarterly observations from 2002 to 2016. Price is calculated as the ex-manufacturer revenues divided by standard units, for each molecule-dosage form-strength presentation within each country and quarter. Outliers are defined as observations where the price is more than 100 times greater or less than the EU average

and those that were more widely available. For products that were sold in a small number of countries, relative prices range from 0.87 to 1.07. However, Table 13 provides a better sense of relative prices, based on widely available products. Countries with relatively low prices at the pack level, on average, include Bulgaria, the Czech Republic, Greece, Hungary, Poland, the Slovak Republic, and Spain. Those with relatively high prices—especially for originator products—include Germany, Ireland, Luxembourg, and Sweden.

Also striking is the difference between originator and generic products. When outliers are excluded, France has originator prices that are about 2% lower than the EU average for originator versions of products that were launched in at least 10 countries, but generic prices that are 31% higher. Similarly, Portugal enjoys relatively low originator prices, but pays about 8% more for generic products. In contrast, the recent EU members generally have prices that are below the EU average for both originator products and generics. There are several potential explanations for these patterns, which merit further research.

Table 13 Prices relative to EU mean, at pack level, products in more than 10 countries

Country	All observations			Outliers excluded		
	Originator	Generic	Total	Originator	Generic	Total
Austria	1.02	1.37	1.08	1.01	1.23	1.07
Belgium	1.00	1.37	1.06	1.00	1.23	1.06
Bulgaria	0.79	1.01	0.84	0.87	0.88	0.85
Czech Republic	0.77	0.95	0.82	0.82	0.86	0.82
Finland	1.05	1.44	1.11	1.05	1.25	1.11
France	0.99	1.38	1.04	0.98	1.31	1.05
Germany	1.14	1.43	1.19	1.15	1.21	1.19
Greece	0.81	1.10	0.88	0.81	1.17	0.89
Hungary	0.80	1.00	0.85	0.84	0.92	0.85
Ireland	1.16	1.69	1.24	1.14	1.64	1.24
Italy	0.93	1.25	0.97	0.93	1.15	0.97
Luxembourg	1.05	1.54	1.13	1.06	1.25	1.14
Norway	0.94	1.25	0.99	0.95	0.98	0.99
Poland	0.77	0.90	0.81	0.82	0.79	0.80
Portugal	0.88	1.13	0.91	0.88	1.08	0.91
Slovak Republic	0.86	1.02	0.90	0.94	0.86	0.90
Slovenia	0.87	1.16	0.93	0.87	1.08	0.93
Spain	0.83	1.04	0.88	0.84	1.00	0.88
Sweden	1.10	1.50	1.14	1.12	1.12	1.14
UK	1.09	1.50	1.11	1.03	1.28	1.11

Data are quarterly observations from 2002 to 2016. Price is calculated as the ex-manufacturer revenues divided by standard units, for each molecule-dosage form-strength presentation within each country and quarter. Outliers are defined as observations where the price is more than 100 times greater or less than the EU average

Patterns are similar when aggregating data to the drug level, as is shown in Tables 14 and 15. As noted earlier, there is greater price dispersion at the drug level than at the pack level. This reflects the larger number of products that are common to many markets. It may also show the use of second-degree price discrimination by producers, who limit opportunities for parallel trade by offering slightly different versions of drugs across countries.

Because the MIDAS data do not capture secret rebates or discounts, prices are measured with error. This mismeasurement probably understates true price variation, at least for on-patent products for which prices are negotiated directly with health agencies. The issues that are associated with a lack of price transparency and measurement are discussed in the following section. It is also worth noting that in the United States, prices that are paid by Medicaid (state-provided insurance for the poor) can also vary substantially by state. A report by the US Department of Health and Human Resources in 2004 found that "[t]he highest paying States unit reimbursement price ranged from 12 to 4073 percent more per drug

Table 14 Prices relative to EU mean, at drug level, products in fewer than 10 countries

Country	All observations			Outliers excluded		
	Originator	Generic	Total	Originator	Generic	Total
Austria	1.02	1.13	0.98	1.00	0.97	0.99
Belgium	0.98	1.72	0.99	0.97	1.02	1.00
Bulgaria	0.94	0.92	0.88	1.00	0.89	0.90
Czech Republic	0.84	0.89	0.84	0.87	0.84	0.83
Finland	1.65	1.48	1.09	1.03	1.12	1.08
France	1.07	1.28	1.01	0.99	1.03	1.01
Germany	1.42	1.57	1.14	1.13	1.09	1.13
Greece	1.06	0.90	0.83	0.84	0.92	0.85
Hungary	1.15	0.90	0.85	0.85	0.88	0.85
Ireland	1.09	1.20	0.97	0.99	0.96	0.99
Italy	1.08	1.11	1.01	1.02	1.03	1.02
Luxembourg	2.40	1.55	1.07	1.04	1.09	1.09
Norway	1.42	1.54	1.21	1.09	1.19	1.13
Poland	1.03	1.13	0.94	1.01	0.92	0.93
Portugal	1.85	1.16	1.01	0.95	1.03	0.99
Slovak Republic	0.94	0.99	0.93	0.94	0.94	0.94
Slovenia	1.14	1.11	1.04	0.98	1.06	1.05
Spain	0.87	1.19	0.87	0.88	0.90	0.88
Sweden	1.36	1.27	1.08	1.07	1.06	1.08
UK	1.52	1.51	1.10	1.13	1.10	1.10

Data are quarterly observations from 2002 to 2016. Price is calculated as the sales-weighted average of ex-manufacturer revenues divided by standard units, across all molecule-dosage form presentations within each country and quarter. Outliers are defined as observations where the price is more than 100 times greater or less than the EU average

than the lowest paying State for the 28 drugs" (US Department of Health and Human Services 2004), and Donohue et al. (2012) also show significant variation across states in prices paid by Medicare Part D (insurance for the elderly). Thus, price dispersion can persist even in a mature single market such as the US, and should not be surprising in the relatively recent EU.

5.1 Regulation of Prices

In all European countries, health coverage is nearly universal. In practice, this means that patients rarely face the true price of the health care that they consume: they may be responsible for a fixed co-pay or percentage, but insurance coverage limits price sensitivity. This situation can easily lead to producers with substantial market power—such as producers of patent-protected pharmaceuticals—setting very high prices. Given the

Table 15 Prices relative to EU mean, at drug level, products in more than 10 countries

Country	All observations			Outliers excluded		
	Originator	Generic	Total	Originator	Generic	Total
Austria	1.11	1.61	1.14	1.09	1.48	1.14
Belgium	0.98	1.27	1.00	0.97	1.09	1.00
Bulgaria	0.78	0.97	0.80	0.85	0.79	0.80
Czech Republic	0.75	0.90	0.77	0.79	0.76	0.76
Finland	1.16	1.58	1.21	1.08	1.33	1.19
France	1.05	1.38	1.07	1.01	1.26	1.08
Germany	1.14	1.42	1.16	1.11	1.19	1.16
Greece	0.76	0.97	0.79	0.79	0.92	0.82
Hungary	0.79	0.98	0.80	0.80	0.81	0.81
Ireland	1.11	1.46	1.14	1.10	1.28	1.15
Italy	1.01	1.36	1.00	0.97	1.14	1.01
Luxembourg	1.03	1.41	1.09	1.07	1.16	1.14
Norway	1.09	1.50	1.15	0.99	1.24	1.09
Poland	0.76	0.88	0.77	0.82	0.73	0.76
Portugal	0.99	1.37	0.97	0.90	1.14	0.98
Slovak Republic	0.87	0.99	0.87	0.91	0.82	0.87
Slovenia	0.97	1.24	1.01	0.93	1.12	1.01
Spain	0.77	0.99	0.80	0.79	0.85	0.80
Sweden	1.18	1.65	1.22	1.10	1.25	1.21
UK	1.18	1.49	1.16	1.06	1.33	1.16

Data are quarterly observations from 2002 to 2016. Price is calculated as the sales-weighted average of ex-manufacturer revenues divided by standard units, across all molecule-dosage form presentations within each country and quarter. Outliers are defined as observations where the price is more than 100 times greater or less than the EU average

important role of EU governments in the provision of health care, such pricing strains health care budgets, and each government has adopted a variety of policies to address this problem. These include direct price controls at different points in the vertical chain (ex-manufacturer, wholesale and retail) as well as indirect price controls, such as limits on reimbursement; see OECD (2008) for a more extensive discussion.

Note that such policies are adopted at the national—not European—level. Article 168 of the Lisbon Treaty states that health policy, including pricing, is a national competence. It is generally acknowledged by economists that the ability to pay for pharmaceuticals may vary across countries, and that a uniform price could have negative effects on access to treatments in poorer countries (Reinhardt 2001). As well, countries may have different priorities and health needs that affect what products are reimbursed by national insurance and the ease of patient access. However, the objective of maintaining policies that are best adapted to national needs is at times inconsistent with the aim of a single market. For example, the policy of free movement of goods across borders that was discussed above should result in price convergence. Such convergence is

generally beneficial to countries where prices are high, and harmful to countries where prices are low. While this may be desirable in many product markets, it undermines the ability of governments in lower-income countries to negotiate lower prices. In addition, many countries have adopted external reference pricing policies, which tie the price in country *i* to those set elsewhere. For example, a policy could state that the price can be no higher than the average of the British, French, and Spanish prices, or must be the minimum of the German, Belgian, and French prices.

A growing body of economic evidence suggests that external reference pricing and parallel trade have important effects on the availability of pharmaceutical products (among others, Kyle 2007; Danzon and Epstein 2008; Maini and Pammolli 2017). Firms have an incentive to delay strategically the introduction of new drugs into countries where prices are expected to be low and that are referenced by many other countries. They may also attempt to ration supply, in order to limit parallel trade (Kyle 2011).

In recent years, the strains on pharmaceutical budgets have prompted calls for greater pricing transparency. Pricing agreements between manufacturers and governments are not always fully public, nor do they specify price alone. For example, an agreement might include quantity limits, volume discounts, and rebates that are paid by the manufacturer. As a result, the public price may not be the true price that is paid. The use of these additional terms and the resulting lack of transparency is likely to be a response to external reference pricing and parallel trade: a government and manufacturer may mutually agree that setting a high public price in exchange for early access to a product—with a secret rebate to offset the high public price—is beneficial to both parties but reduces the information that is available to assess relative prices. Note that this lack of price transparency could increase access, particularly if poorer countries receive larger discounts. However, other patterns of discounts are also possible: smaller countries with limited bargaining power might receive smaller discounts.

6 Conclusion

The establishment of a European single market resulted in a number of significant changes to institutions and market structure in pharmaceuticals. In markets with high fixed costs, we generally expect larger markets to see more entry and competition. In pharmaceuticals, these costs include those that are associated with obtaining regulatory approval as well as pricing and reimbursement negotiations. For generic products, the costs of assessing and avoiding patent barriers may also be important components. The creation of a pan-EU marketing authorization via the EMA—complemented by the mutual recognition procedure—appears to have significantly reduced the fixed costs of product launch, and consequently increased access to new products in Europe. New chemical entities that have been introduced since 1990 reach more EU countries, and more quickly, following accession to the EU and when the centralized procedure is used. However, most pharmaceutical products pre-date the EU, and their presence accounts for substantial differences in the product mix that is available across countries.

Price differences of pharmaceuticals are large and persistent across EU member states—even when considering homogeneous products with low transportation costs. This is, at least in part, by design: pricing is a national competence, and governments may have different preferences or budget constraints that result in different prices, and this could be welfare-enhancing relative to a single European price. Free movement of goods, or parallel trade, has not eliminated these differences, and nor has external reference pricing. What is perhaps more surprising is the persistent price differences for older (generic) products, which bear little relationship to purchasing power or national income differences. For such products, patent barriers are minimal, and there are no dynamic innovation concerns relevant to price-setting by governments. In this case, a uniform price that is close to marginal cost should be the outcome of a competitive and integrated market.

Going forward, with the increased use of the centralized procedure and greater uniformity of patenting, convergence in product availability is likely to continue. Generic entry costs should be lower for products that are approved centrally. As more of these centrally-approved products become eligible for generic entry, we may also observe higher levels of competition in more countries. Future research may consider other opportunities to reduce entry costs, such as greater coordination of health technology assessments. However, as long as health care remains a national competence, the interaction of many country-level policies will likely result in many persistent differences in the use and pricing of pharmaceuticals as well as other health technologies.

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